GIMA
PROFESSIONAL MEDICAL PRODUCTS

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INCONTINENCE TENS

User Manual

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

M-28341-Rev.0.06.12

CE 0434

Fabbricante/Manufacturer:
Everyway Medical Instruments Co., Ltd.
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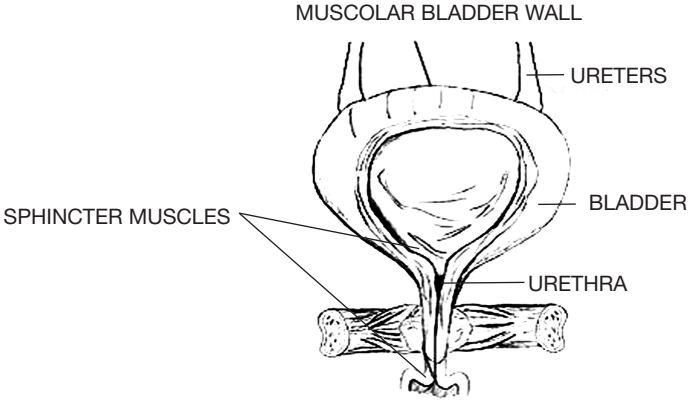
Chapter 1: INTRODUCTION

Bladder Control for Women

Urinary incontinence is an inability to hold your urine and/or faeces until you get to a toilet. It is often temporary, and it always results from an underlying medical condition.
Women experience incontinence twice as often as men.
Pregnancy, childbirth, menopause, and the structure of the female urinary tract account for this difference. But both women and men can become incontinent from neurological injury, birth defects, strokes, multiple sclerosis, and physical problems associated with ageing.
Older women, more often than younger women, experience incontinence. But incontinence is not inevitable with age. Incontinence is treatable and often curable at all ages.
Incontinence in women usually occurs because of problems with muscles that help to hold or release urine. The body stores urine (water and waste products removed by the kidneys) in the bladder, a balloon-like organ. The bladder connects to the urethra, the tube through which urine leaves the body.
During urination, muscles in the wall of the bladder contract, forcing urine out of the bladder and into the urethra. At the same time, sphincter muscles surrounding the urethra relax, letting urine pass out of the body. Incontinence will occur if your bladder surrounding the urethra suddenly relax.

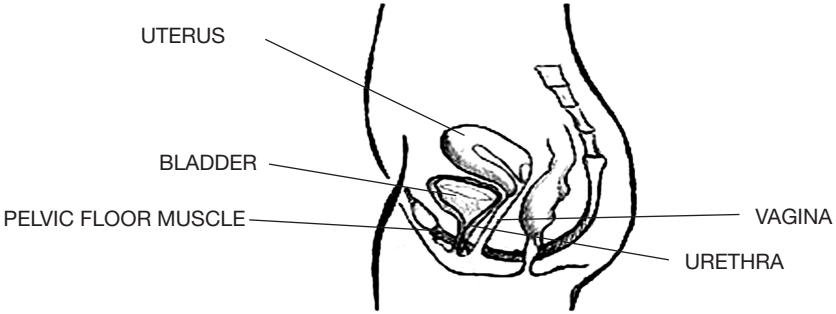


The Types of Incontinence

There are different types of Urinary Incontinence. The most common types are Stress, Urge and Mixed incontinence.

Stress incontinence

Leakage of small amounts of urine when you sneeze, strain, cough, exercise or make sudden movements. It is particularly common in women and occurs when the bladder neck and the other mechanisms that act to hold urine in the bladder are not working properly.
(see Figure 2)



Urge Incontinence

An overactive bladder cause leakage of large amounts of urine at unexpected times, including sleep. You may experience a strong sudden urge to go to the toilet so that you are not able to hold on, or have to go so frequently that it upsets your life.

Mixed Incontinence

A combination of both Stress and Urge incontinence.

Electrical Stimulation

Brief doses of electrical stimulation can strengthen muscles in the lower pelvis in a way similar to exercising the muscles. Electrodes are temporarily placed in the vagina or rectum to stimulate nearby muscles. This will stabilize overactive muscles and stimulate contraction of urethral muscles. Electrical stimulation can be used to reduce both stress incontinence and urge incontinence.
The Stress Incontinence programme is based on strengthening the muscles of the pelvic floor. Once muscular strength has been improved, these muscles are better able to resist urinary leakage caused by external pressure being applied to the bladder.
A lower-frequency current has a beneficial effect in reducing the involuntary contractions in Urge incontinence. It works by slowing down the rate of false signals sent to the brain. A lower frequency is also used as a part of the Stress programme as it improves muscle quality: blood flow and resistance to fatigue are also increased.

Chapter 2:
CONTRAINDICATIONS AND PRECAUTIONS

Incontinence can have many causes. The incontinence stimulator should never be used unless the cause and source of incontinence have been diagnosed by a medical practitioner.

Precautions

1. Read instruction manual before use of the incontinence stimulator.
2. We emphasize that patient with an implanted electronic device (for example, a pacemaker or any implanted electronic devices) should not undergo incontinence stimulation treatment without consulting doctor.
3. If incontinence therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is re-evaluated by the physician or therapist.
4. Do not use an incontinence stimulator while operating machinery or vehicles.
5. Turn the device off before applying or removing probe.
6. The EV-807E Incontinence stimulator device has no AP/APG protection. Do not use it in the presence of explosive atmosphere and flammable mixture.
7. Only use with Everyway probes.
8. Do not touch the metal electrodes of this probe after turning the device on except for normal operation according to Chapter 12.
9. This device is in compliance with the requirements of IEC/EN 60601-1-2. However, there is no guarantee that electromagnetic interference will not occur in a particular way of use. Should it occur the user is encouraged to switch off the equipment and try to minimize the interference by increasing the separation between this device and the device which is located as the probable source or recipient of it. Please refer below lable:

Rated maximum power of transmitter (W)	150 Khz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.1167	0.1167	0.2334
0.1	0.369	0.369	0.7378
1	1.167	1.167	2.334
10	3.69	3.69	7.378
100	11.67	11.67	23.34

Separation Distance in m

Interference may occur in the vicinity of equipment marked with the following symbol:

Warnings

1. The incontinence stimulator should not be used during pregnancy.
2. The device should be used only under the continued supervision of a physician.
3. The user must keep the device out of the reach of children.
4. Keep the control unit dry and away from source of heat.

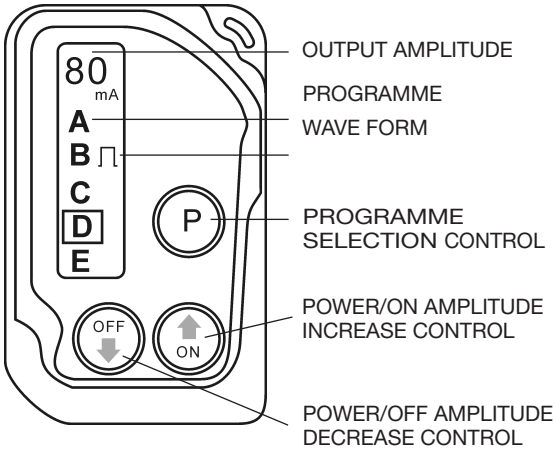
Contraindications

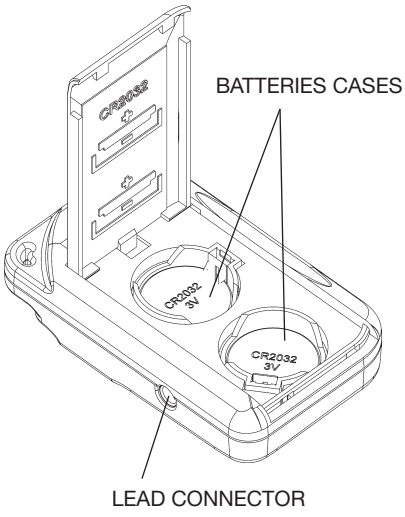
1. Do not use incontinence stimulator if you suffer from any muscle disorder.
2. Do not use incontinence stimulator if a bladder or vaginal infection is present.
3. Do not use incontinence stimulator if you have been diagnosed or treated for cervical cancer.
4. Do not use incontinence stimulator if you have, or have had, epilepsy

Chapter 3: GENERAL DESCRIPTION

The EV-807E incontinence stimulator is a battery operated pulse generator that sends electrical impulses through probe electrodes tothe pelvic floor muscle. The device has one controllable output channel. A probe electrode can be connected to the output channel. The device has 5 preset programme. The type of programme and intensity of output is controlled by press buttons.

Chapter 4: CONSTRUCTION





Chapter 5:
TECHNICAL SPECIFICATIONS

	MECHANISM	TECHICAL DESCRIPTION
01	Channel	Single channel
02	Pulse Amplitude	Adjustable, 0-80mA, Max output 80mA (peak to peak) into 500ohm load.
03	Output Voltage	Adjustable, 0-40V, Max output 40V (peak to peak) into 500ohm load.
04	Wave Form	Asymmetrical Rectangular Biphasic Pulse.
05	Power Supply	Two LITHIUM CR2032 Batteries
06	Size	77.6mm (L) x 47.8mm (W) x 17.2mm (H)
07	Weight	49.5 grams (2 batteries included)
08	Pulse Rate	Pre-setting, 1~100 Hz
09	Pulse Width	Pre-setting, 150 µs, 200 µs or 250 µs
10	Programme	A, B, C, D, E, five pre-set programme of options.
11	Programme A, B, C, E	The programme details of A, B, C, E are as follows. Parameters are preset at fixed values. The 2 seconds ramp time including 1 second ramp up, and 1 second ramp down. Each programme will be repeated in a cycle pattern constantly.
12	Programme D	Programme D is composed with 12 sections in varied pulse rate. Each section contains 30 contractions. The 2 seconds ramp time including 1 second ramp up, and 1 second ramp down. The complete programme lasts 60 minutes with 360 contractions. Then repeated in a cycle pattern constantly. The details of the programme are as given below.
13	Operating Condition	Temperature: 0°~40°C Relative Humidity: 30%~75% Atmosphere Pressure: 700Hpa~1060Hpa
14	Remark	There may be up to a +/-5% tolerance of all parameters and +/-20% tolerance of amplitude & voltage.

Programme	Rate (Hz)	Width (µs)	Contraction (Sec.)	Relaxation (Sec.)	Ramp (Sec.)	Cycle (Sec.)
A	35	250	4	8	2	14
B	40	200	6	15	2	23
C	10	250	5	3	2	10
D	(See Column 12)					
E	20	250	5	5	2	12

Section	Rate (Hz)	Width (µs)	Contraction (Sec.)	Relaxation (Sec.)	Ramp (Sec.)	Cycle (Sec.)
1	7	150	4	4	2	10
2	8	150	4	4	2	10
3	9	150	4	4	2	10
4	10	150	4	4	2	10
5	11	150	4	4	2	10
6	12	150	4	4	2	10
7	13	150	4	4	2	10
8	14	150	4	4	2	10
9	15	150	4	4	2	10
10	16	150	4	4	2	10
11	12	150	4	4	2	10
12	7	150	4	4	2	10

Chapter 6: REPLAECEABLE PARTS

The replaceable accessories are as given below.

NO.	PARTS
01	Vaginal Probe Electrode
02	Anal Probe Electrode
03	Surface Electrodes
04	Lithium CR2032 Battery
05	Battery Cover
06	Lead Connector
07	Main PCB

Please do not try to replace other parts of unit.

Chapter 7: ACCESSORIES & LABEL

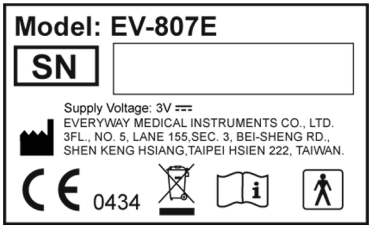
Accessories

Ref. No.	Description	Q'ty
PR-02A	Vaginal Probe	1
KB-24	Lead wire	1
GC-04	Lithium CR2032 Battery	4
	Instruction Manual	1
	Carrying Pouch	1
	Rope	1

*See page 16 for more information about the option of probe electrodes and surface electrodes.

Label

The label attached to the back of device contains important information about this device: model, serial number(started with manufacturing year and week of the device), supply voltage, the name of manufacturer, CE number and classification. Please do not remove.

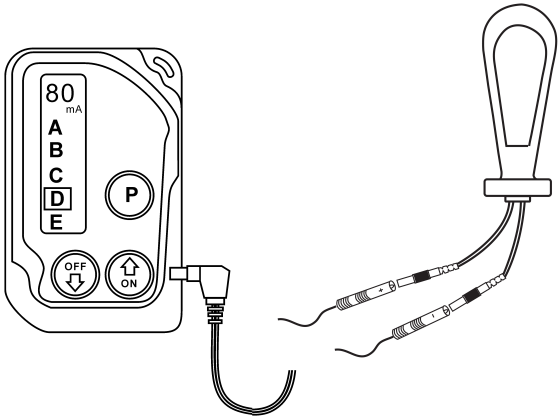

Model: EV-807E
SN
Supply Voltage: 3V ⎓
EVERYWAY MEDICAL INSTRUMENTS CO., LTD.
3FL., NO. 5, LANE 155,SEC. 3, BEI-SHENG RD.,
SHEN KENG HSIANG,TAIPEI HSIEN 222, TAIWAN.
CE 0434

Chapter 8: GRAPHIC SYMBOLS

1. Note Operating Instructions
2. Degree of Electrical Protection BF
3. Do not insert the plug into AC power supply socket.
4. Direct Current (DC power source)
5. Increase Intensity/Power On
6. Decrease Intensity/Power Off
7. Consult Instructions for use
8. Manufacturer
9. SN Serial Number

Chapter 9: ATTACHMENT OF PROBE TO THE UNIT

The lead provided with the system inserts into the jack socket located on side of the device. Holding the insulated portion of the connector, push the plug end of the lead into the jack socket.



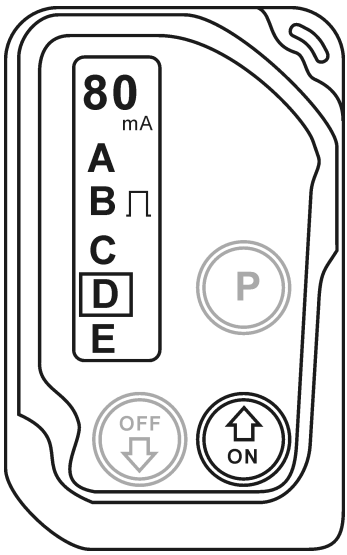
Chapter 10:
MAINTENANCE & CLEANING OF PROBE ELECTRODE

The internal probe electrode is for a single user only. It must be cleaned with cold soapy water or a pad soaked in surgical spirit and then rinsed in clean running water before and after each treatment. Dry it with a paper towel after cleaned. The wire of probe can be cleaned by wiping with a damp cloth.

Chapter 11:
ADJUSTING THE CONTROLS

Power On / Amplitude Increase Control
Power can be turned on when this button is pressed for 3 seconds. Press it again and amplitude will be increasing lin early from 0 mA to the desired level.
From 0 to 10mA, amplitude is increased by 2mA each step, and from 10 to 80mA by 1mA each step. The value is visible on the LCD.
When power is turned on, there is 60 seconds for you to adjust amplitude after a programme is selected.
When the electrical output is started, the LCD will show the wave form of each pulse on the right side of LCD.
When the programme is in relaxation, the amplitude cannot be adjusted.

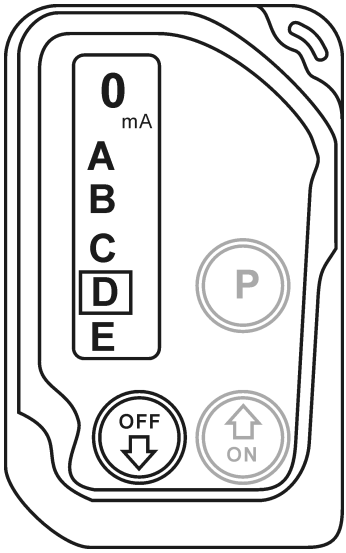
a. ON



Power Off / Amplitude Decrease Control

Amplitude can be decreased
by pressing this button.
From 80 to 10mA, it will be decreased
by 1mA each step. From 10
to 0mA, it will be decreased
by 2mA each step.
Press the button continuously,
the amplitude will be decreased
linearly until the level desired is reached.
When amplitude is “0 mA”, power
can be turned off by pressing
this button for 3 seconds.
When amplitude is at “0 mA”,
the device will be shut off automatically
after one minute if it is not used.

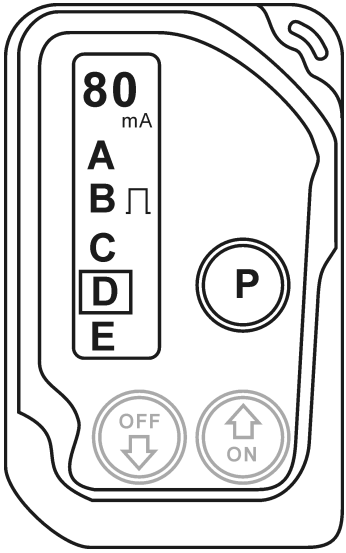
b. OFF



c. P: Programme Selection/Urgent Stop Control

Programme can be changed
by pressing this button when power
is turned on and the amplitude is “0mA”.
When amplitude is higher than1mA,
output will be terminated immediately
and the amplitude return to “0mA”
when this button is pressed.
When amplitude is returned to “0mA”, wait
6 seconds before re-adjusting
the unit.

c. P

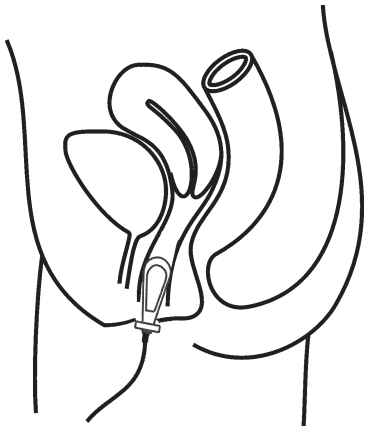


Chapter 12: INSTRUCTIONS FOR USE

The internal probe electrode is for a single user only. It must be cleaned

1. Use the toilet before beginning the treatment, if necessary
2. Clean the probe as per the instructions.
3. Make sure the stimulator is turned off before use.
4. Connect the cable of probe to the device as per the instructions.
5. Apply a thin coating of lubricating gel on the vagina opening or apply a small amount of gel on the tip of the probe.
6. Insert the probe into the vagina, (make sure the metal contacts facing sideways) until the flange at the base of the probe is just on the outside and is vertical.

* Lay down or sit in a comfortable position with your knees up and your back supported by a cushion or pillow for your comfort.

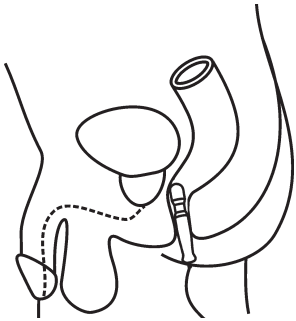


7. Press the “On” button for 3 seconds and the power will be turned on.
8. Press “P” button to select a programme desired. There are 5 programs available. The details of them are described in specifications.
9. Press the “On” button to increase amplitude
10. Press the “off” button to decrease amplitude. Once a programme is selected, you have 60 seconds to adjust the amplitude to a comfortable level by pressing On and Off buttons. After the programme is started, it will be repeated in a cycle pattern as per described in specifications.

11. After use, press the “P” button to stop output. Then press the “off” button for 3 seconds(When “0mA”), the power will be turned off.
12. Disconnect the lead from the control unit.
13. Remove the probe from the vagina by holding the flange.
14. Clean the probe as per the instructions.

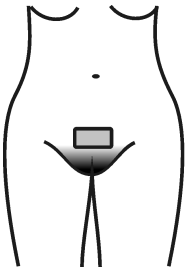
Optional Anal Probe

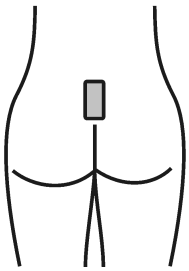
The EV-807E Incontinence stimulator can also be used with an anal probe. Place probe as shown below, and proceed as for incontinence stimulation.

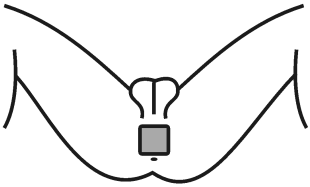


Optional Surface Electrodes

The EV-807E Incontinence stimulator can also be used with surface electrodes.
Place the electrodes as shown below, and proceed as for continence stimulation.







Chapter 13: CHECK & REPLACE BATTERIES

Over time, in order to ensure the functional safety of the stimulator, changing the battery is necessary.

1. Make sure that power is turned off and probe or electrodes are removed from body.
2. Slide the battery compartment cover and open.
3. Remove the battery from the compartment.
4. Insert the battery CR2032 into the compartment. Please make sure that the + sign is facing upwards. Remove flat batteries at once as corrosion may damage the unit.
5. Replace the battery compartment cover and press to close.
6. The LCD will count down for 6 seconds from “666” to “111” before its standard menu is revealed.

* The new lithium battery must be packed separately and store in cool dry area.
Do not collide both batteries. Do not dispose of batteries on a fire or incinerator.

Chapter 14: MAINTENANCE, TRANSPORTATION AND STORAGE OF DEVICE

1. Non-flammable cleaning solution is suitable for cleaning the device. Note: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the pouch to ensure that the unit is well protected before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Pack batteries separately. Put the device and accessories in pouch and keep it in cool dry place.
6. The packed stimulator device should be stored and transported under the temperature range of -20°C ~ + 60°C, relative humidity 20%~ 95%, atmosphere pressure 500 hPa ~ 1060 hPa.

Chapter 15: SAFETY-TECHNICAL CONTROLS

For safety reasons, check your incontinence stimulator each week based on the following checklist.

1. Check the device for external damage.
   - Deformation of the housing.
   - Damaged or defective output sockets.
2. Check the device for defective operating elements.
   - Legibility of inscriptions and labels.
   - Make sure the inscriptions and labels are not distorted.
3. Check the usability of accessories.
   - Probe undamaged.

Please consult your distributor if there are any problems with device and accessories.

Chapter 16: MALFUNCTIONS

Should any malfunctions occur while using the EV-807E Incontinence stimulator, check

- Whether the cable of probe is correctly connected to the device. The cables should be inserted completely into the sockets.
- Whether the batteries are well-inserted.
- Whether the LCD reveals the menu. If necessary, insert 2 new batteries.
- For possible damage to the cable probe. Change the probe if any damage is detected.

* If there is any other problem, please return the device to your distributor. Do not try to repair a defective device.

Chapter 17: CONFORMITY TO SAFETY STANDARDS

The EV-807E Incontinence stimulator devices are in compliance with the EN 60601-1-2:2001 and EN 60601-1:1990+A1:1993+A2: 1995+A13:1996 safety standards.

Chapter 18: WARRANTY

All EV-807E Incontinence stimulator devices carry a warranty of one year from the date of delivery. The warranty applies to the stimulator only and covers both parts and labor relating thereto.
The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alteration or disassembly by unauthorized personnel.

Manufacturer

Everyway Medical Instruments Co., Ltd.
3Fl., No.5, Lane 155, Sec. 3, Bei-Sheng Rd.,
Shen Keng Hsiang, Taipei Hsien 222, Taiwan.

Representative in the EU

Physio-Med Services
7-23 Glossop Brook Business Park,
Surrey Street, Glossop,
Derbyshire, SK13 7AJ, England.

Information for distributor

Please contact the above mentioned manufacturer for technical support and documentation when necessary.

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Chapter 19: OPTION OF ELECTRODES

This EV-807E is supplied with one standard type of probe electrode. If you to need to to purchase a new probe electrode or adhesive electrodes, please contact the manufacturer, EU representative (See page 17) or the local dealer for more information. The option of electrodes suitable for the unit are as follows.

A. Probe Electrodes with Female Plug Connection

MODEL #	TYPE	DIAMETER	MODEL #	TYPE	DIAMETER
PR-02	Vaginal	28mm	PR-06	Rectal	14mm
PR-03	Vaginal	25mm	PR-13	Rectal	19.6mm
PR-04	Vaginal	20mm			

B. Probe Electrodes with 2 pig tail Connection

MODEL #	TYPE	DIAMETER	MODEL#	TYPE	DIAMETER
PR-02A	Vaginal	28mm	PR-06A	Rectal	14mm
PR-03A	Vaginal	25mm	PR-13A	Rectal	19.6mm
PR-04A	Vaginal	20mm			
PR-16A	Vaginal	33mm			

C. Adhesive Electrodes

MODEL #	SHAPE	SIZE
KF100		40X53mm
KF200		65X70mm

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product.This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.
Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devicesor software due to outside agents such as: voltage changes, electro-magnetic elds, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

This manual must be read and fully understood by all relevant persons prior to use of the unit.